

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte LESLIE D. MICHELSON, LEONARD ROSENBERG  
and LANCE CONVERSE

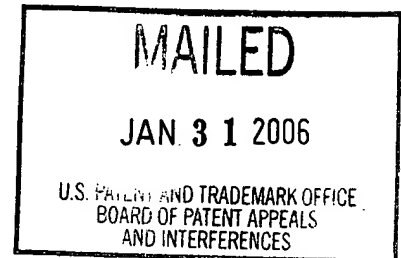
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Appeal No. 2005-2501  
Application No. 09/923,385

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ON BRIEF

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Before HAIRSTON, KRASS and JERRY SMITH, Administrative Patent Judges.  
KRASS, Administrative Patent Judge.

**DECISION ON APPEAL**

This is a decision on appeal from the final rejection of claims 2-15 and 129-151.

The invention pertains to on-line interactive forums for promoting the exchange of information among clinical study sponsors, clinical study investigators, and potential participants in the clinical study.

Representative independent claim 2 is reproduced as follows:

2. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

- (a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;
- (b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;
- (c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person;
- (d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice;
- (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and
- (f) storing answers submitted by the person or caregiver in the database.

The examiner relies on the following references:

Knight	2002/0099570 A1	7-2002
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Larkin Marilyn, "Where to find clinical trials on the Web", The Lancet, April 11, 1998, Vol. 351, No. 9109, page 1140.

Anonymous, "TVisions Wins Top Web Externet Award; recognized for Creative Life-Saving Site", Business Wire, 7/1/1999, No. 42844318, page 1 [TVisions].

Baldwin, Gary, "System makes it easier to link patients to clinical trials", American Medical New, 11/16/1998, Vol. 41, No. 53, pp. 25.

Center Watch Website: <http://www.centerwatch.com> [CenterWatch].

Claims 14 and 15 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 2-15 and 129-151 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner offers Baldwin, website of CenterWatch and Knight with regard to claims 2, 4-14, and 130-151, adding, alternatively, TVisions with regard to claims 3 and 129, and Larkin with regard to claim 15.

Reference is made to the brief (Supplemental Brief filed June 14, 2004) and answer for the respective positions of appellants and the examiner.

### OPINION

We turn, first, to the rejection of claims 14 and 15 under 35 U.S.C. § 112, second paragraph.

It is the examiner's position that claim 14 is indefinite because it includes the limitation of "other off-line sources." The examiner explains that because specific listed off-line sources (ostensibly "telephone, regular mail, facsimile") appear in the claim, it is somehow indefinite to include the phrase "and other off-line sources."

We disagree. Clearly, the recitation of "other off-line sources" is merely a list extender. The skilled artisan would clearly understand that the answers mentioned in claim 14 may be provided by "telephone, regular mail, facsimile, and other off-line sources" (emphasis ours). While the complained-of term makes the scope of the claim broader, to include any type of off-line source, it does not make the claim indefinite.

With regard to claim 15, the examiner contends that the scope of the term, "the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database" cannot be determined. The examiner explains that one cannot tell whether the person or caregiver is required to present genetic sequence information when registering with the database (in which case, alleges the examiner, the claim is missing an important step) or whether the disease condition of interest input by the person or caregiver at registration is associated with particular genetic sequence information. The examiner also queries

whether there are clinical trials related to specific studies relating genetic sequence information to a specific disease that relates to the patient's or caregiver's disease condition of interest.

We again find the examiner's concern to be more of breadth than indefiniteness. The claim merely requires the step of automatically determining to further include a reference to genetic sequence information associated with a person registered in the database. It does not matter how the genetic sequence information got into the database. It is just there, and this permits the examiner to use any reference teaching the use of genetic sequence information associated with a person registered in a database that determines whether to provide a person or caregiver with notice of a given clinical study; but it does not permit the examiner to merely contend that the claim is indefinite for not giving more details about the genetic sequence information. The examiner might have a point if there was some question as to what "genetic sequence information" meant or if there was no known way to provide such information, but this is not the case in the instant situation.

Accordingly, we will not sustain the rejection of claim 15 under 35 U.S.C. § 112, second paragraph.

Thus, we have not sustained either the rejection of claim 14 or of claim 15 under 35 U.S.C. § 112, second paragraph.

Turning, now, to the rejections under 35 U.S.C. § 103, each rejection depends, at least in part, on the reference to Knight. There is an issue as to whether Knight is a viable reference. Therefore, we must decide this issue before we decide whether the rejection of the claims under 35 U.S.C. § 103 is proper on its merits. It is axiomatic that if Knight is not a viable reference under 35 U.S.C. § 103, through 35 U.S.C. § 102, then we need not reach a decision on the merits of the rejection.

Knight is a United States Patent Application Publication, with a publication date of July 25, 2002, based on an application filed August 23, 2001. The instant application was filed on August 8, 2001, but is based on a continuation of PCT/US01/02936, filed January 29, 2001, which claims the benefit of provisional application number 60/178,634, filed January 28, 2000.<sup>1</sup>

Since Knight was published on July 25, 2002 and the instant application was filed on August 8, 2001, if Knight qualifies as prior art at all, it must be under 35 U.S.C. § 102 (e) which permits the use of a United States Patent, or Patent Application Publication, as a reference, though the publication date is after the filing date of the application in question, so long as the Patent Application Publication has a filing date prior to that of the instant application in question. In this case, Knight's filing date is

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<sup>1</sup>While the papers in our file show a filing date of January 28, 2000 for provisional application number 60/178,634, appellants indicate that this date should be January 26, 2000. In any event, this will make no difference to the outcome here.

August 23, 2001. This, in itself, would not defeat the instant application date of August 8, 2001. However, Knight claims the benefit of provisional application number 60/227,484, filed August 24, 2000.

The examiner argues that appellants are not entitled to the provisional filing date of January 28 (or 26), 2000 because that provisional application disclosure did not support the now claimed "presenting a questionnaire" and that Knight is entitled to the provisional filing date of August 24, 2000, predating the PCT filing date of the instant application of January 29, 2001, thus being a viable reference against the instant claims.

Appellants argue that they are entitled to the January 28 (or 26), 2000 provisional application filing date because, while "presenting a questionnaire" is not explicitly disclosed therein, the skilled artisan would have understood that such was, indeed, disclosed in the provisional application. More particularly, appellants argue that page 4 of that application recites that "the present invention is directed to a method and system for creating secure databases...and allowing access by appropriate parties to these databases over a network" and that page 8 recites that the "system also includes a web site 320 through which a variety of information may be accessed." Moreover, appellants contend that page 9 of the provisional application describes the use of system software to support account sign-up and management, demographics capture, personalization of target audiences and the matching of "participant entered data"

against trial criteria. See page 7 of the supplemental brief, wherein appellants cite the following language from page 9 of the provisional application:

The system includes software that supports account sign-up, management, demographics capture, and personalization of target audiences. A core personalization and registration infrastructure supports ad-hoc user properties, profile, and behavioral data collection, content targeting, useful site and usage reporting, and specified user views. The views provide the specific information each sponsor needs, and ensures confidential and proprietary data is shielded from competitors.

The software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data.

It is appellants' position that while "automatically presenting questionnaires" is not recited *verbatim*,

...there can hardly be any argument that web-based software for supporting "account sign-up, management, [and] demographics capture" and which "supports ad-hoc user properties, profile and



behavioral data collection, content targeting, useful site and usage reporting, and specified user views" is referring to the use of some type of questionnaire in order to obtain the information from the user. If there were any doubt, the application's description of comparing trial criteria to "participant entered data" removes it (Supplement brief-page 7).

Since appellants contend that there is no other imaginable scenario as to how the system would perform the described functionality without presenting a questionnaire to the user, and the examiner has identified no alternative interpretation of the cited passage, appellants contend that there is sufficient support in the provisional application for "automatically presenting a questionnaire," as claimed.

The examiner appears to argue that the question is not whether there is support in the provisional application for "questionnaire," as such, but, rather whether there is support for "automatically presenting a questionnaire *associated with the given clinical study* to the person or caregiver" (emphasis added by the examiner-see page 18 of the answer). The examiner contends that while he did find support for this claimed limitation in both the instant application and the PCT application filed on January 29, 2001, he could not find support for this feature in the Provisional Application Number 60/178,634.

We have reviewed the arguments of appellants and the examiner regarding this matter and we find, on balance, that the evidence favors appellants in concluding that Provisional Application Number 60/178,634 did, indeed, provide support for the now-claimed “automatically presenting a questionnaire associated with the given clinical study to the person or caregiver.”

It appears reasonable to us that the cited passage from page 9 of the provisional application does provide support, albeit not *verbatim*, for “automatically presenting a questionnaire.” The artisan would have understood from the system including software that supports “account sign-up, management, demographics capture, and personalization of target audiences;” from “behavioral data collection...and specified user views” that a user is indeed inputting information that is requested of him/her; i.e., there is some type of questionnaire presented to the user in order to acquire this information. Also, since there is a “comparison of the participant profile” (it appears that a participant profile would have been collected by responses to a questionnaire) “to the trials protocol criteria,” it is clear that questionnaire-entered data from a user is compared to clinical criteria.

Thus, it is apparent to us that appellants’ provisional application does provide support for “automatically presenting a questionnaire.” It may be presumed from the examiner’s response (answer-pages 18-19) that the examiner does not disagree with the provisional application’s support for “automatically presenting a questionnaire,” and

the examiner is really arguing that it is the automatically presenting a questionnaire “associated with the clinical study” to the person or caregiver, that is not adequately supported. However, if that is the case, we still disagree with the examiner because the cited passage from page 9 of the provisional application states that there is a “comparison of the participant profile to the trials protocol criteria.” Accordingly, it would appear that the data entered into the questionnaire is compared to the trials protocol criteria. That is, the participant profile, acquired from a questionnaire, being compared to the trials protocol criteria, means that the questions in the questionnaire have some relation to, i.e., are “associated with,” the given clinical study.

Having found that there is support in Provisional Application No. 60/178,634 for “automatically presenting a questionnaire associated with the given clinical study to the person or caregiver...,” as claimed, we find that appellants are entitled to the filing date, January 28 (or 26), 2000, of that provisional application. Accordingly, appellants’ effective filing date predates the earliest filing date that could be accorded to Knight. Thus, even if Knight is accorded an August 24, 2000 filing date, based on Knight’s provisional application (an issue on which appellants and the examiner disagree), Knight would still not be a viable reference based on 35 U.S.C. § 102 (e), since the filing date of appellants’ provisional application is prior to the earliest possible filing date accorded to Knight.

We have not sustained the rejection of claims 14 and 15 under 35 U.S.C. § 112, second paragraph, and we have not sustained the rejection of claims 2-15 and 129-151 under 35 U.S.C. § 103. Accordingly, the examiner's decision is reversed.

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Appeal No. 2005-2501  
Application No. 09/923,385

Page 13

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